Section 5

510(k) Summary

JUN 0 7 2013

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4196 (801) 253-6932 Michaela Rivkowich March 19, 2013 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Prelude® Sheath Introducer Vessel Dilator for Percutaneous Catheterization Vessel Dilator for Percutaneous Catheterization
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Prelude® Sheath Introducer Vessel Dilator for Percutaneous Catheterization K073035 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1310 FDA Product Code: DRE Review Panel: Cardiovascular	
Intended Use	The Prelude® Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.	
Device Description	The Prelude® Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath is equipped with a side arm terminating in a 3-way stopcock. The sheath hub contains an integral hemostasis valve and a suture ring. The subject sheath introducer has a radiopaque marker tip. The device is marketed with and without an appropriately sized guide wire.	

Comparison to Predicate Device	The subject device has the same technological characteristics (i.e., as the predicate device). The only change that was made was to the radiopaque marker tip material.

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Prelude® Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standard:

- ISO 11070:1998, *Sterile, single-use intravascular catheter introducers*
- ANSI/AAMI/ISO 11135-1:2007, *Sterilization of health care products – routine control of a sterilization process for medical devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995
- ISO 10993-3:2003, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*
- ISO 10993-4:2002 (Amd.1:2006), *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood*
- ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-10:2002 (Amd. 1:2006), *Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type hypersensitivity*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ASTM F756-08:2008, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- United States Pharmacopeia 33, National Formulary 28, 2010 <151> Pyrogen Test

The following is a list of all significant testing that was successfully completed:

Safety & Performance Tests cont.	Design Verification • Tortuous path test • Force at break • Radiopacity • Tip insertion/peel back • Dilator drag • Stiffness Biocompatibility • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Genotoxicity • Hemolysis • Thrombogenicity • Complement Activation • Chemical Characterization The results of the testing demonstrated that the subject Prelude® Sheath Introducer met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Prelude® Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Prelude® Sheath Introducer, manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Merit Medical Systems, Inc.
C/O Michaela Rivkowich
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K130791
Trade/Device Name: Prelude® Sheath Introducer
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: May 9, 2013
Received: May 10, 2013

Dear Ms. Michaela Rivkowich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number: K130791

Device Name: Prelude® Sheath Introducer

Indications for Use:
The Prelude® Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lisa M. Lim -S 2013.06.07 14:45:21 -04'00'